

# Directive

9180.81

9/6/07

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## **QUALITY MANAGEMENT PROGRAM** **REQUIREMENTS FOR OFFICIAL SERVICE PROVIDERS**

### **1. PURPOSE**

This directive establishes the requirement that all entities authorized by the Grain Inspection, Packers and Stockyards Administration (GIPSA) to provide services under the authority of the U.S. Grain Standards Act or the Agricultural Marketing Act of 1946 must maintain a Quality Management Program in accordance with the GIPSA Quality Standard (attachment).

### **2. AUTHORITY**

This directive is established under the authorities of the United States Grain Standards Act (7 U.S.C. 71-87), the Agricultural Marketing Act of 1946 (7 U.S.C. 1621-1627), as amended, and the regulations established thereunder.

### **3. BACKGROUND**

GIPSA relies on a variety of arrangements with other government and private entities to carry out the requirements of the U.S. Grain Standards Act and the Agricultural Marketing Act of 1946, as amended, to achieve its mission. These entities provide American agriculture with a variety of sampling, inspection, and testing services in accordance with specific GIPSA policies and procedures. Compliance with the policies and procedures is essential to promote accurate, impartial, and standardized results—the true value of the official certificate. To further strengthen the services provided by these various entities, GIPSA has established a Quality Management Program consistent with internationally recognized quality management principles. All entities authorized to provide official services on behalf of GIPSA, commonly referred to as official service providers (OSP), will develop and maintain a quality management program in accordance with the GIPSA Quality Standard.

### **4. DEVELOPMENT OF OSP QUALITY MANUALS**

OSP managers must develop a quality manual in accordance with the GIPSA Quality Standard. At the request of OSP managers, GIPSA's Field Management Division (FMD) may assist OSP's with developing their quality manuals by providing comments and advising on the contents of their manuals. For FMD assistance submit the manuals by email to [beth.e.hayden@usda.gov](mailto:beth.e.hayden@usda.gov) and [henry.c.greenwood@usda.gov](mailto:henry.c.greenwood@usda.gov).

OSP must submit their completed manual to GIPSA's Compliance Division Review Branch no later than six months from the date of the GIPSA provided quality management training. The Review Branch will conduct a 'desk audit' by reviewing the manual for conformance to GIPSA's quality standards. Send all manuals by email for a desk audit to [karen.w.guagliardo@usda.gov](mailto:karen.w.guagliardo@usda.gov) based on the date of training.

## **5. GIPSA AUDITS**

### **a. Adequacy or Desk Audit**

The Review Branch will conduct an adequacy or desk audit of new or significantly revised quality manuals to assess conformance to the GIPSA Quality Standard. These audits involve the examination of documentation.

OSP must send to the Review Branch reports from their annual audit and QMS review annually.

### **b. On-Site Audit**

On-site audits will begin after the Review Branch determines that the final quality manuals are adequate. The Review Branch will conduct on-site audits and will assess noncompliance and non-conformance in the following manner.

#### **(1) Minor**

Part of a requirement has been addressed. Corrective action must be made within 60 days of receipt of the audit report.

#### **(2) Major**

An entire requirement has been ignored or not implemented. Corrective action, or a plan of corrective action, must be provided to the Review Branch within 15 days of receipt of the audit report.

#### **(3) Accumulation of Minor Deficiencies**

An accumulation of minor deficiencies are considered "Major" when the auditor observes that the Quality Management System is not effective. Corrective action, or a plan of corrective action, must be provided to the Review Branch within 15 days of receipt of the audit report.

### **c. Surveillance Audit**

Surveillance audits are conducted as a followup to determine that a corrective action or a plan of corrective action is implemented or when determined appropriate by the Review Branch.

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Audit findings will serve as a key component in assessing the overall performance of OSP's as it relates to renewal of designations, contracts, and other such arrangements.

**6. QUESTIONS**

Contact FMD at 202-720-0228 regarding the draft quality manuals and the Review Branch at 202-720-8262 regarding the final quality manuals and audits.

For additional information regarding GIPSA's Quality Management Program refer to the following website:

<http://www.gipsa.usda.gov/GIPSA/webapp?area=home&subject=osp&topic=qms>

*/s/ David R. Shipman*

David R. Shipman  
Deputy Administrator

Attachment

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United States Department of Agriculture



Grain Inspection,  
Packers and Stockyards Administration

# **GIPSA Quality Standard**

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A Management Standard for Official Service Providers

September 06, 2007

All previous documents and revisions are obsolete.  
Dispose and replace with this document.

USDA GIPSA  
Stop 3630  
1400 Independence Ave., SW  
Washington, DC 20250-3630

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# **Quality Management System Overview**

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## **INTRODUCTION**

A Quality Management System (QMS) is a management tool that considers all parts of an organization related to quality, including management responsibility, customer focus, resource management, service delivery, and the continual improvement of the operation. A QMS can be described as a network of interconnected processes. A process is a series of steps or actions that begin with an input and result in an output. When a group of processes are put together, it becomes a system of processes working together collectively to achieve the common objective of customer satisfaction. In early manufacturing systems, Henry Ford initiated several processes to form an assembly line. By putting those processes together, he was able to efficiently and economically provide customers with affordable and reliable quality automobiles. In a modern QMS, each process within an organization, from creating an effective work environment to ensuring the quality of service delivery, are interrelated to ensure consistent delivery of a product or service.

Developing and implementing a QMS helps an organization focus on quality management objectives. For best results when seeking to achieve such objectives, a quality system must be managed according to specific quality management standards. In today's marketplace, a business must document its conformance to these quality standards to ensure that tasks are performed on time and within the structured goals of the organization.

To lead and operate an organization successfully, it is necessary to direct and control it in a systematic and transparent manner. Success can result from implementing and maintaining a management system that is designed to continually improve performance while addressing the needs of its customers. Managing an organization encompasses quality management among other management disciplines.

Eight quality management principles are identified and internationally accepted as the best means top management can use to lead an organization towards improved performance. Those management principles form the basis of the Grain Inspection, Packers and Stockyards Administration (GIPSA) Quality Standard developed by the United States Department of Agriculture (USDA), GIPSA, Federal Grain Inspection Service (FGIS), under which an Official Service Provider (OSP) must operate when providing inspection and related services on behalf of GIPSA.

## **BACKGROUND**

FGIS facilitates the marketing of U.S. grain and related agricultural products by establishing standards for quality assessments, regulating handling practices, and managing a network of Federal, State, and private laboratories known as the official system. The official system provides impartial, user-fee funded official inspection and weighing services under the authority of the United States Grain Standards Act (USGSA), and the Agricultural Marketing Act of 1946 (AMA), as amended. FGIS also establishes standard testing methodologies for accurately and

consistently measuring the quality of grain and commodity. Similar to the official standards for grading grain and commodities, the official GIPSA Quality Standard play an integral part in how services are delivered within the official system. Customers of the official system will experience a higher degree of confidence in the product or service provided when the OSPs in the official system conform to a quality system based on an established management standard.

Conformance to the GIPSA Quality Standard will ensure that an OSP can clearly demonstrate the following:

- a) Consistent quality products and services produced through the use of documented procedures,
- b) Establishment of management and assessment procedures,
- c) Implementation of corrective and preventive actions,
- d) Retention of records and data describing the quality of the product or service, and
- e) Continuous improvements embraced throughout the organization.

## **PURPOSE**

This GIPSA Quality Standard was developed based on internationally accepted quality management principles under which an organization should operate. GIPSA adopted these principles as its quality management philosophy because it correlates with the core values and concepts of many quality improvement programs which emphasize:

- a) Understanding and meeting customer needs and requirements,
- b) Considering processes in terms of added value,
- c) Obtaining best quality results of process performance and effectiveness, and
- d) Continual improvement of processes.

This GIPSA Quality Standard is part of a wider effort to introduce more flexibility, accountability, and innovation into the GIPSA/OSP relationship. The end result will be high performing OSPs that drive progress within the official system. Each OSP must prepare its own unique Quality Management System that fits its organizational culture and meets the requirements set forth in the GIPSA Quality Standard. In addition to adhering to the GIPSA Quality Standard, the OSP must meet certain selection criteria and specific requirements.

## GLOSSARY OF TERMS

Term	Definition
<b>Audit</b>	Systematic, independent, and documented process for obtaining evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled. These are performed internally (informal) and externally (formal).
<b>Compliance</b>	The affirmative indication or judgment that the supplier of a product or service has met the requirements of the relevant laws, regulations, SOPs, handbooks, and directives. Individuals and companies comply with the regulations.
<b>Conformance</b>	Refers to adherence to quality management standards. If your organization meets these requirements, then your organization conforms to these requirements.
<b>Corrective Action</b>	This term is used to define the correction of non-conformity or non-compliance. The intent of this term in the GIPSA Quality Standard is to document the steps that are taken to remove or eliminate the causes of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence or to make quality improvements. Corrective actions address actual problems. In general, the corrective action process can be thought of as a documented problem solving process.
<b>Customer</b>	Any entity (organization or person) who receives products or official services from the OSP. For the purposes of the GIPSA Quality Standard, GIPSA is not considered an OSP customer since the OSP must enter into an agreement with GIPSA.
<b>Document</b>	Refers to information and the paper, sign board, computer monitor, etc., that is used to bring it into existence. A document can be digital or physical. There are many types of documents; for example, specifications, quality manuals, quality plans, records, and procedure documents. A document is considered living because it changes over time.

Term	Definition
<b>Documentation</b>	All of the information generated by the OSP to conform to the GIPSA Quality Standard. This includes documents, records, handbooks, SOPs, and any other materials.
<b>Documented Procedures</b>	A document that describes an activity indicating who is responsible for the activity, where the activity occurred, and the frequency; a document that provides information to carry out a process or activity in an orderly manner. The QMS requires eight documented procedures.
<b>Official Service Provider (OSP)</b>	An organization granted the authority to perform work on behalf of GIPSA through designations, delegations, cooperative agreements, and contracts.
<b>Outreach Methods</b>	Proactive efforts undertaken by the OSP to build and foster new and existing customer relationships. Examples of outreach activities may include, but are not limited to, advertising, personal contacts, newsletters, interviews, questionnaires, customer satisfaction surveys, and promoting awareness of GIPSA policies and procedures.
<b>Preventive Action</b>	This term is used to define the correction of a potential non-conformance or a potential noncompliance. It documents the steps that are taken to remove the causes of potential nonconformities or to make quality improvements. Preventive actions address potential problems, ones that have not yet occurred. In general, the preventive action process can be thought of as a risk analysis process with a documented procedure.
<b>Process</b>	In general, a process uses resources to transform inputs into outputs using a set of interrelated or interacting activities; a series of steps leading to a desired result; a set or series of conditions, operations, or steps working together to produce a desired result. In every case, inputs are turned into outputs because some kind of work, activity, or function is carried out. This includes any process that falls within the scope of the QMS ranging from billing to inspecting to interacting with GIPSA.

Term	Definition
<b>Product</b>	An output that results from a process. A product is normally thought to have physical, tangible properties but can be also be intangible, a thing or an idea, hardware or software, information or knowledge, a process or procedure, a service or a function, a concept or creation. An example of a tangible GIPSA product would be a certificate. An intangible product would be the delivery of the service; i.e., the timeliness and accuracy.
<b>Purchased Product or Service</b>	A product or service that is purchased through a supplier. A service may have intangible properties. Examples include software for generating certificates, contract samplers, or bags for holding samples.
<b>Quality Coordinator</b>	The individual within the OSP responsible for implementing and maintaining the QMS. This responsibility cannot rest with the top manager since this individual must report to the top manager.
<b>Quality Management System (QMS)</b>	A system of business practices that includes management responsibility, resource management, service delivery, and measurement, analysis, and improvement to direct and control an OSP with regard to quality.
<b>QMS Manual or Quality Manual</b>	A document that demonstrates the ability of the OSP to meet the requirements of the Quality Management Standards. It follows the sequence of the Standards and also includes the documented procedures and specific requirements in the Addendum. It can be a paper manual or an electronic manual.
<b>QMS Review</b>	A review to evaluate the overall performance of an organization's QMS and to identify improvement opportunities. These reviews are a formal documented activity carried out by the OSP top management and are done on a regular basis. This process is referred to as a Management Review.
<b>Quality Objectives</b>	Something sought, or aimed for, related to quality; goals, targets, or aims concerning product, service, processes, or systems related to quality. Must be measurable and achievable. They will change over time. In some cases, a baseline must be established prior to setting an objective for improvement.

Term	Definition
<b>Record</b>	A historical artifact that contains objective evidence showing conformance to the QMS. Records are always documents what has happened in the past; typically a record is considered “dead” since it cannot be changed. For example, a form that is completed is a record.
<b>Resources</b>	Includes personnel, finances, information and techniques (such as SOPs, handbooks, etc.), knowledge, skill, energy, and infrastructure (facilities, machines, tools, equipment, and technologies).
<b>Root Cause</b>	The source of defects, problems, or conditions. When performing corrective actions, the root cause must be discovered to prevent the problem from occurring again.
<b>Standard Operating Procedures (SOP) or Work Instruction</b>	A document that provides detailed information to control and carry out an activity in a step-by-step manner, including the associated inputs and outputs. Such a procedure defines the work that should be done, and explains how it should be done, who should do it, and under what circumstances. In addition, it explains what authority and what responsibility has been allocated, which supplies and materials should be used, and which documents and records must be used to carry out the work. This includes those procedures developed by the OSP and those published by GIPSA.
<b>Service</b>	A customer-oriented result that includes all work provided on behalf of GIPSA. The result is produced when the OSP performs activities that are oriented towards meeting customer needs and expectations. Examples include sampling, inspection, and weighing of commodities under the USGSA and AMA.
<b>Service Delivery</b>	Customer-oriented activities that are carried out by an organization to meet customer needs and expectations. A primary example is the official service performed by an OSP when it applies the Official U.S. Standards for Grain and standard testing methodologies in an impartial manner to accurately and consistently measure grain quality.

Term	Definition
<b>Standard</b>	A standard is a written document. It is a set of rules that control how people develop and manage materials, products, services, technologies, processes, and systems.
<b>Supplier</b>	An organization or person that provides a product or service to customers. Customers can be either internal or external to the supplier organization. External suppliers include retailers, distributors, manufacturers, utility companies, and services.
<b>Top Management</b>	A person or group of people with decisionmaking authority, whether it is the Owner, Chief Executive Officer (CEO), or Board of Directors. This authority includes making decisions that direct and control OSP operations at the highest level.
<b>Validation</b>	Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled. For example, retesting a sample and getting the same result is validation that the original test was done correctly.
<b>Verification</b>	Confirmation that the requirements stated in standards, work instructions, SOPs, or specifications have been met. For example, observing that an SOP is followed correctly is verification that the activity has been completed as planned.

# **GIPSA Quality Standard**

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## **ELEMENT 1: GENERAL LEGAL RESPONSIBILITIES**

*All inspection and related activities performed on behalf of GIPSA must comply with the United States Grain Standards Act (7 U.S.C. 71 et seq.), regulations (7 CFR Part 800, 801, 802, 810) and the Agricultural Marking Act of 1946, as amended (7 CFR Part 868), instructions, methods, and policy and procedures, as applicable. Major requirements are listed below or are included in the GIPSA Quality Standard; however, this list is not inclusive. All handbooks, directives, laws, and regulations necessary for conducting “official service” can be found at the following: <http://www.gipsa.usda.gov>.*

All OSPs must:

- a) Provide all products or services in the organization’s assigned area, including official inspection services, as required by agreement, regulations, instructions, and handbooks.
- b) Charge fees without discrimination and in accordance with a GIPSA approved fee schedule and maintain records of all fees and billing.
- c) Report to the responsible GIPSA contact person or office, information which shows or may show a violation of any provision of the USGSA, regulations, or instructions and information on any instructions which have been issued to agency personnel by GIPSA personnel, or by any other person which are inconsistent with the USGSA, regulations, or instructions.
- d) Provide sufficient security to ensure that official samples, records, equipment, forms, or GIPSA owned property are reasonably secure from theft, alteration, or misuse.
- e) Respond to noncompliances and nonconformances in a timely manner.
- f) Comply with all applicable Federal, State, or local regulations such as those for safety and sanitation.
- g) Notify the appropriate GIPSA contact person or office of any changes that may affect the quality of the product or service being provided on behalf of GIPSA prior to the change being made.
- h) Allow access to any structure, work area, records, and documents that are used while manufacturing a product or performing services on behalf of GIPSA.
- i) Rotate personnel, where feasible, among elevators and other facilities as is necessary to preserve the integrity of the official inspection and weighing system.

- j) Ensure that no officer, director, stockholder, employee, or other related entity has a conflict of interest related to commercial grain merchandizing, transporting, storage, or other related activity.
- k) Not perform unofficially services included as official services in their designation.
- l) Maintain a certificate control system for all official certificates it receives, issues, voids, or otherwise renders useless.
- m) Use only personnel licensed by GIPSA to perform official services.

**Contractors or cooperators performing service for GIPSA** must meet the following quality standard requirements (Elements 2-9) in addition to all legal conditions stated in the contract or in the agreement.

## **ELEMENT 2: GENERAL QUALITY STANDARD REQUIREMENTS**

*An OSP must develop, document, implement, and maintain a QMS and continually improve its effectiveness while meeting the requirements set forth in this Management Standard.*

OSP must accomplish the following:

- a) Identify and document QMS processes and their application throughout the organization in a QMS manual,
- b) Determine the criteria and methods required to ensure operational effectiveness and control of these QMS processes,
- c) Ensure the availability of resources necessary to support the operation, monitoring, measuring, and analyses of these QMS processes,
- d) Supply products and deliver services that meet customer needs in compliance with GIPSA requirements, and
- e) Take necessary actions to achieve planned goals while continually improving the QMS processes.

These QMS processes must be managed by the OSP in accordance with the requirements of this Management Standard.

## **ELEMENT 3: DOCUMENTATION REQUIREMENTS**

*When establishing a QMS, an organization must document its quality system including everything it must do in support of the QMS prior to assigning responsibilities, resources, and processes. The type and extent of the documentation will depend on the size and complexity of the OSPs business operations as well as the nature of its products, services, and processes, the degree of formality of communication systems and the level of communication skills within the organization, and the organizational culture.*

### 3.1 QMS MANUAL

The OSP must prepare and maintain a quality manual to include the following:

- a) General information about the OSP,
- b) Scope of the QMS which describes specific services provided on behalf of GIPSA, and
- c) All elements required by the QMS Management Standard including all documented procedures and records (*Reference Appendix A: Quick Reference for a consolidated listing*).

### 3.2 CONTROL OF DOCUMENTS

The OSP must provide a ***documented procedure*** that defines how they perform the following:

- a) Approve documents for adequacy prior to issue,
- b) Review, update as necessary, and re-approve documents,
- c) Ensure the changes and current revision status of documents are identified,
- d) Ensure the relevant versions of applicable documents are available at points of use,
- e) Ensure that documents remain legible and readily identifiable, and
- f) Prevent the unintended use of obsolete documents, and apply suitable identification when they are retained for any purpose.

The OSP must maintain a list of all documents identifying the current versions and whether the document is of internal or external origin.

### 3.3 CONTROL OF RECORDS

The OSP must provide a ***documented procedure*** that defines how they perform the following:

- a) Establish and maintain records to provide evidence of conformity to QMS requirements,
- b) Establish controls needed for the identification, storage, protection, retention, and disposition of all records,
- c) Ensure all records are legible, readily identifiable, and retrievable, and
- d) Establish, maintain, and monitor a system for providing certificates, if applicable.

# Management Responsibility

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## ELEMENT 4: MANAGEMENT COMMITMENT

*Management establishes unity of purpose and direction of the organization by creating and defining the organization's policies and objectives and by ensuring that they are communicated to the entire organization.*

### 4.1 QUALITY OBJECTIVES

The OSP top management must ensure that quality objectives are defined and managed for relevant functions and levels within the organization. The quality objectives must be measurable.

### 4.2 QMS PLANNING

The OSP top management must ensure the following:

- a) The planning of the QMS is carried out in order to meet the General Quality Standard Requirements stated in ELEMENT 2, as well as the quality objectives, and
- b) The integrity of the QMS is maintained when changes to the QMS are planned and implemented.

### 4.3 RESPONSIBILITY AND AUTHORITY

The OSP top management must ensure that responsibilities and authorities are defined and communicated within the organization. For example, these responsibilities and authorities must be defined in job descriptions, the QMS manual, and an organizational chart.

### 4.4 QUALITY COORDINATOR

The OSP top management must appoint a Quality Coordinator, who, irrespective of other responsibilities, has the responsibility and authority to do the following:

- a) Ensure that processes needed for the QMS are established, implemented, and maintained,
- b) Report to top management on the performance of the QMS and any need for improvement, and
- c) Ensure the promotion of awareness of customer requirements throughout the organization (e.g., by communicating customer expectations and seeking ideas for improvement).

### 4.5 INTERNAL COMMUNICATION

The OSP top management must ensure that appropriate communication processes are established within the organization. Communication takes place regarding the effectiveness of the QMS, for example, through regular staff meetings, email notifications, or newsletters. Mechanisms to communicate must be established for employees at *all levels* within the organization.

## **4.6 QMS REVIEW**

The OSP top management must review the organization's QMS, at regularly planned intervals (at least annually), to ensure its continuing suitability, adequacy, and effectiveness. The QMS review must assess opportunities for improvement and the need for changes to the QMS, including the quality objectives.

Records, such as an agenda and minutes, from QMS reviews must be maintained (*Reference 3.3 – Control of Records*).

### **4.6.1 REVIEW INPUT**

Inputs to QMS reviews must at least include the information on the following:

- a) Results of internal and external audits,
- b) Customer feedback, such as surveys and complaints,
- c) Process performance and service delivery issues including status of quality objectives,
- d) Status of preventive and corrective actions,
- e) Followup actions from previous QMS reviews,
- f) Changes that could affect the QMS or other areas such as organizational changes, new projects or processes, external changes, new regulations, or new technologies, and
- g) Recommendations for improvement.

### **4.6.2 REVIEW OUTPUT**

Outputs from QMS reviews must include any decisions and actions related to the following:

- a) Improvement of the effectiveness (results) of the QMS and its processes,
- b) Service delivery improvements related to customer requirements, and
- c) Resource needs.

Responsibilities for actions must be noted with due dates.

## **ELEMENT 5: CUSTOMER FOCUS**

*Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements, and should strive to exceed customer expectations.*

## 5.1 CUSTOMER REQUIREMENTS

The OSP must ensure customer requirements are determined and are met with the aim of enhancing customer satisfaction. The OSP must determine requirements specified by the customer, including the following:

- a) The requirements for service delivery and post-delivery activities,
- b) Statutory and regulatory requirements related to official services, and
- c) Any additional requirements determined by the OSP.

## 5.2 CUSTOMER SATISFACTION

The OSP must provide a ***documented procedure*** and maintain records (*Reference 3.3 – Control of Records*) to assess customer satisfaction that defines and describes how they perform the following:

- a) Current outreach methods,
- b) Address customer complaints and/or disputes, and
- c) Use of information to make continuous improvements.

The OSP must determine and implement effective arrangements for communicating with customers in relation to service delivery, inquiries, contracts or service requests, including amendments and customer feedback.

## 5.3 CUSTOMER PROPERTY

The OSP must exercise care with property (including intellectual property such as confidential information) belonging to a customer while it is under the OSP control or being used by the OSP. The OSP must identify, verify, protect, and safeguard customer property provided for use or incorporation into the service delivery. If any customer property is lost, damaged, or found to be otherwise unsuitable for use, this must be reported to the customer and records maintained (*Reference 3.3 – Control of Records*). Customer-owned property must be in good working order when used to perform any work on behalf of FGIS.

# Resource Management

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## ELEMENT 6: RESOURCES

*An OSP cannot operate without adequate resources including personnel, buildings, equipment, and environment.*

### 6.1 PERSONNEL

People at all levels who are fully involved in an organization's quality system are the essence of an organization. Their full involvement enables their abilities to be used for the organization's benefit. All OSP personnel performing work affecting quality must be competent on the basis of appropriate training, skills, and experience. The OSP must have a **documented procedure** to:

- a) Determine the necessary competence for all personnel performing work affecting service delivery,
- b) Provide training or take action to ensure competency needs are met,
- c) Evaluate the effectiveness of training or other actions taken,
- d) Ensure that employees are aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives,
- e) Ensure personnel conflicts of interest are monitored and addressed, and
- f) Monitor the performance of its employees.

Records of supervision, training, skills, and experience must be maintained (*Reference 3.3 – Control of Records*).

### 6.2 INFRASTRUCTURE

The OSP must determine, provide, and maintain the infrastructure needed to achieve conformity to service delivery requirements in accordance with GIPSA requirements. Infrastructure includes:

- a) Facilities such as buildings, workspace, and associated utilities,
- b) The availability, maintenance, and use of GIPSA-approved or allowed equipment such as measuring devices, machines, and tools, and
- c) Supporting services, as applicable such as transportation or communication technology.

### **6.2.1 CONTROL OF EQUIPMENT**

The OSP must establish processes to ensure the use of GIPSA approved or allowed equipment is controlled in a manner that is consistent with GIPSA requirements. To ensure equipment produces valid results, the OSP must:

- a) Identify equipment to enable the calibration status to be determined,
- b) Calibrate or verify equipment at specified intervals or prior to use, against measurement standards traceable to GIPSA measurement standards,
- c) Adjust or re-adjust equipment as necessary,
- d) Safeguard equipment from adjustments that would invalidate results, and
- e) Protect equipment from damage and deterioration during handling, maintenance, and storage.

Records of the results of calibration and verification (i.e. checktesting) must be maintained (*Reference 3.3 – Control of Records*).

### **6.2.2 WORK ENVIRONMENT**

The OSP must determine and manage the infrastructure and work environment needed to achieve conformity to service delivery requirements in accordance with GIPSA requirements.

### **6.3 PURCHASE VERIFICATION**

An OSP must ensure that any purchased products and services used to provide official services conform to specified requirements. Purchase verification must include the following:

- a) A procedure for the development of purchase requirements prior to communicating with the supplier,
- b) The requirements for approval of product, procedures, processes and equipment as well as qualification of personnel,
- c) Criteria for supplier selection, evaluation, and re-evaluation,
- d) Evaluation and selection of suppliers based upon their ability to supply products or services to meet the OSP requirements, and
- e) The inspection or other activities necessary to ensure that any products or services purchased from a third-party supplier meet QMS or GIPSA requirements.

The type and extent of control applied to the supplier and the purchased product or service must be dependent upon the effect of the purchased product on the final product or service delivery. Records of the results of evaluations and any necessary actions arising from the evaluation must be maintained (*Reference 3.3 – Control of Records*).

# **Service Delivery**

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## **ELEMENT 7: SERVICE DELIVERY PROCESSES**

*A consistent product or service that meets customer requirements is achieved more efficiently when activities and related resources are managed as a process.*

### **7.1 SERVICE DELIVERY**

The OSP must plan and carry out production and service delivery under controlled conditions. Controlled conditions include, as applicable, the following:

- a) The availability of information such as handbooks, directives, and other GIPSA publications that describe the scope of services (i.e., grain inspection),
- b) A sufficient number of qualified personnel,
- c) The availability of SOPs,
- d) The availability, maintenance, and use of GIPSA approved or allowed equipment,
- e) The implementation of monitoring and measurement to support QMS processes,
- f) The implementation of release, service delivery, and post-delivery activities, and
- g) A system to maintain integrity and traceability for all official services.

### **7.2 QUALITY ASSURANCE /QUALITY CONTROL PLAN**

An OSP providing grain inspection service must establish and maintain the grading ability and performance of its inspectors through a structured and documented internal Quality Assurance/Quality Control (QA/QC) plan including:

- a) Monitoring and evaluating interpretive results;
- b) Monitoring and evaluating equipment and testing results;
- c) Utilizing a defined sample selection method including either;
  - i) Random sample selection, or
  - ii) Targeted by inspector, grain, damage, or condition;
- d) Taking corrective action when trends, biases and inspection differences are indicated by the monitoring data;
- e) Submitting to GIPSA all required data within the required timeframe; and

- f) Attending training sessions when required by GIPSA.

Records must be kept of QA/QC alignment activities.

### **7.3 PRODUCTS OR SERVICES**

The OSP must monitor and measure the characteristics of the product or service to verify that requirements have been met. This must be carried out in accordance with applicable SOPs.

Evidence of conformity with the acceptance criteria must be maintained. Records must indicate the person(s) authorizing release of the product or service.

Product release and service delivery must not proceed until all the requirements have been satisfactorily met, unless otherwise approved by a relevant authority, and where applicable, by the customer.

### **7.4 CONTROL OF NONCONFORMING PRODUCTS OR SERVICES**

The OSP must have a *documented procedure* to ensure that products or services which do not conform to requirements are identified and controlled to prevent unintended use or delivery. The OSP must address nonconforming products and services prior to delivery by taking action to correct the detected nonconformity. After release, the OSP must take appropriate action to issue a correct product.

Records of the nature of nonconformities and any subsequent actions taken must be maintained (*Reference 3.3 – Control of Records*).

## Measurement, Analysis, and Improvement

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### ELEMENT 8: MONITORING AND MEASUREMENT

*A factual approach to decisionmaking is based on the analysis of data and information.*

#### 8.1 INTERNAL AUDITS

The OSP must conduct internal audits at regularly planned intervals (at least annually) to determine if the QMS does the following:

- a) Conforms to the regulatory requirements for providing services on behalf of GIPSA,
- b) Conforms to the requirements of this Management Standard,
- c) Conforms to specific contractual requirements, if applicable,
- d) OSP established requirements as stated in its QMS Manual, documented procedures, and work instructions, and
- e) Is effectively implemented and maintained.

An audit program must be planned, taking into consideration the status and importance of the processes and areas to be audited as well as the results of previous audits. The audit criteria, scope, frequency and methods must be clearly defined. Selection of auditors and conduct of auditors must ensure objectivity and impartiality of the audit process. Internal auditors must meet OSP qualifications and must not audit their own work.

The responsibilities and requirements for planning and conducting audits and for reporting results and maintaining records must be defined in a ***documented procedure***.

Records of internal audit results and followup actions must be maintained (*Reference 3.3 – Control of Records*).

#### 8.2 PROCESSES

The OSP must apply suitable methods for monitoring and, where applicable, measurements of the QMS processes. These methods must demonstrate the ability of the processes to achieve planned results, including analyzing characteristics and trends to identify opportunities for preventive action. When planned results are not achieved, corrective action must be taken.

### ELEMENT 9: CONTINUAL IMPROVEMENT

*Continual improvement of the organization's overall performance should be a permanent objective of the organization.*

The OSP must continually improve the effectiveness of the QMS through the use of the following:

- a) Quality objectives,
- b) Audit results,
- c) Analysis of data relating to customer satisfaction, conformity to products and services, and suppliers,
- d) QMS reviews, and
- e) Preventive and corrective actions.

### **9.1 PREVENTIVE ACTION**

The OSP must determine action to eliminate the causes of potential nonconformities to prevent occurrence. Preventive actions must be appropriate to the effects of the potential problems.

A *documented procedure* must be established to define requirements for:

- a) Determining potential nonconformance and their causes,
- b) Evaluating the need for action to prevent occurrence of nonconformities (root cause),
- c) Determining and implementing action needed,
- d) Recording results of preventive action taken, and
- e) Reviewing preventive action taken to determine effectiveness.

Records of preventive actions must be maintained (*Reference 3.3 – Control of Records*).

### **9.2 CORRECTIVE ACTION**

The OSP must take corrective action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective action must be appropriate to the problem encountered.

A *documented procedure* must be established to define requirements for:

- a) Reviewing nonconformities (including customer complaints),
- b) Determining the causes for nonconformity (root cause),
- c) Evaluating the need for actions to ensure that nonconformities do not recur,
- d) Determining and implementing the corrective action needed,

- e) Recording results of corrective action taken, and
- f) Reviewing and assessing corrective action taken to determine effectiveness.

Records of corrective actions must be maintained (*Reference 3.3 – Control of Records*).

## **APPENDIX : Quick Reference**

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This QMS Management Standard requires the following procedures to be documented and records to be maintained (other procedures and records must be maintained as required by GIPSA laws and regulations or as part of the OSP internal operations and business practices).

<b>Documented Procedures</b>	<b>Records Maintained</b>
<b>3.2 Control of Documents</b>	<b>4.6 QMS Reviews</b>
<b>3.3 Control of Records</b>	<b>5.2 Customer Satisfaction</b>
<b>5.2 Customer Satisfaction</b>	<b>5.3 Customer Property</b>
<b>6.1 Personnel Management</b>	<b>6.1 Personnel</b>
<b>7.2 Quality Assurance/Quality Control Plan</b>	<b>6.2.1 Control of Equipment</b>
<b>7.4 Control of Nonconforming Products or Services</b>	<b>6.3 Purchase Verification</b>
<b>8.1 Internal Audits</b>	<b>7.3 Product or Services (Release)</b>
<b>9.1 Preventive Action</b>	<b>7.4 Control of Nonconforming Products or Services</b>
<b>9.2 Corrective Action</b>	<b>8.1 Internal Audits</b>
	<b>9.1 Preventive Actions</b>
	<b>9.2 Corrective Actions</b>